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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,548	07/16/2003	Joel D. Oxman	57179US004	8448

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EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,548	OXMAN ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-4 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11-21-03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claims 1-4 are indefinite insofar as the basis for the percent by weight calculation is not set forth, e.g., percent by weight based on the total weight of the composition, percent by weight based on the weight of water, etc. See Honeywell Intl., Inc. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite unless the particular method of measurement is recited.)

2) The terms "low viscosity" and "highly viscous" in claims 1, 3 and 4 are relative terms which render the claims indefinite. The terms are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Note that the only discussion of any specified "degree" provided by the specification reflects not simply a change from "low" to "high", but an at least ten-fold change. See the last paragraph of p. 2 of the instant specification; see also p. 5, lines 11-22.

3) Claim 2 is incomplete insofar as it depends on a non-existent (canceled) claim.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Vacanti (USP 5,944,754).

The prior art discloses aqueous hydrogel compositions for tissue regeneration, which are applied to a body surface by painting with a brush, or in aerosolized form from a spraying device such as an air brush or manual spray pump (col. 8, lines 26-45). The body surface may be the oral cavity (col. 2, lines 38). Since compositions applied to the oral cavity would also contact (or at the very least be capable of contacting) the teeth they are "dental" compositions, where the term "dental" is interpreted as broadly as is reasonable in light of the teachings of the instant specification. The hydrogel compositions comprise 5-25 percent (col. 7, lines 57-59) of a viscosity modifier (col. 7, lines 57-59), including thermoreversible aqueous Pluronic hydrogels. See the passage bridging col. 5, line 61 to col. 6, line 5.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti (USP 5,944,754).

The prior art is discussed in the "Anticipation" section supra, and teaches administration of thermoreversible gels to the oral cavity via painting with a brush, or by aerosolizing with a "spraying device". The prior art differs from the instant claims insofar as it does not explicitly disclose, *ipsissima verba*, an aerosol container having a propellant, but it does state that "such devices are commonly used in surgery to spray air or water over a desired surface" (col. 8, lines 26-45). Given that the prior art explicitly discloses aerosols and suggests the use of "well known" spraying devices, the use of a device as simple and widely available as an aerosol container containing a propellant would surely have been obvious therefrom.

2) Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oxman et al (USP 6,312,666) or Trom et al (USP 6,669,927 or USP 6,312,667), each primary reference being considered individually and separately and each being taken in view of Vacanti (USP 5,944,754).

Each primary reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Oxman et al (USP 6,312,666) discloses aqueous dental (tooth whitening) compositions comprising 5 to 40 weight percent of a thermoreversible hydrogel, e.g., F-127 Pluronic (col. 5, lines 10-15), which are administered either by painting with a brush or directly from a container (col. 6, lines 21-31). Trom et al (USP 6,669,927) and Trom et al (USP 6,312,667) are substantially cumulative of Oxman et al. Each primary reference differs from the instant claims insofar as it does not specify administration via an aerosol.

The secondary reference is discussed in the "Anticipation" section, and subsection "1)" immediately supra as well. It teaches that thermoreversible hydrogels may be administered to the oral cavity either by painting with a brush, or by aerosolizing (with a propellant) from a container. Accordingly, it would have been obvious to have used either method to apply the compositions of any of the three primary references; there are any of a number of sound reasons one would be motivated to use an aerosol spray instead of painting with a brush, e.g. because the former is less messy than the latter.

3) Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oxman et al (USP 6,312,666) or Trom et al (USP 6,669,927 or USP 6,312,667), each primary reference being considered individually and separately and each being taken in view of Hill et al (USP 5,032,387).

Oxman et al (USP 6,312,666) discloses aqueous dental (tooth whitening) compositions comprising 5 to 40 weight percent of a thermoreversible hydrogel, e.g., F-127 pluronic (col. 5, lines 10-15) which are administered either by painting with a brush, or directly from a container (col. 6, lines 21-31). Trom et al (USP 6,669,927) and Trom et al (USP 6,312,667) are substantially cumulative of Oxman et al. Each primary reference differs from the instant claims insofar as it does not specify administration via an aerosol.

The secondary reference discloses aqueous spray dentifrices and teaches that, when they are administered via a metered (propellant containing) aerosol, they provide a uniform thin film while encouraging user to employ the tongue to assist in spreading the composition over the teeth (col. 8, lines 3-20). The secondary reference differs from the instant claims insofar as it does not specifically disclose thermoreversible hydrogels, and moreover the amounts of surfactant used therein are substantially less than the claimed minimum of 10 percent by weight.

It would have been obvious to have applied the primary reference compositions from a metered aerosol container, motivated by the desire to provide a uniform thin film as taught by the secondary reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614